

**Citation:**

Hu FB, Li TY, Colditz GA, Willett WC, Manson JE. Television watching and other sedentary behaviors in relation to risk obesity and type 2 diabetes mellitus in women. JAMA. 2003 Apr 9; 289(14):1785-91.

**PubMed ID:** [12684356](#)

**Study Design:**

Prospective cohort study design

**Class:**

B - [Click here](#) for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To examine the relationship between various sedentary behaviors, especially daily prolonged television(TV) watching, and risk of obesity and type 2 diabetes.

**Inclusion Criteria:**

The Nurses' Health Study cohort was established in 1976.

- Female
- Registered Nurses
- Aged 30-55 years
- Resident of 1 of 11 states in the United States

**Exclusion Criteria:**

- Women with diagnosed cardiovascular disease, cancer, diabetes in 1992
- Women who were already obese(body mass index(BMI) $\geq$ 30) in 1992 or earlier cycles.

**Description of Study Protocol:**

**Recruitment** :Details were not provided.

**Design**:Prospective cohort study design

**Blinding used (if applicable)**

**Intervention (if applicable)**

**Statistical Analysis**

- Person-time for each participant was calculated from the date of return of the 1992 questionnaire to the date of confirmed type 2 diabetes(for diabetes analysis only), the year of the first reported obesity(for obesity analysis only), death from any cause , or June 1,1998, whichever came first.
- Incidence rates of obesity or type 2 diabetes were obtained by dividing the number of cases by person-years in

each category of average time spent on each sedentary behavior (e.g., watching television).

- Relative Risks (RRs) were computed as the incidence rate in specific category of TV watching divided by that in the reference category.
- Tests for linear trend across increasing categories of average time spent watching TV were conducted by treating the categories as a continuous variable and assigning the middle score for the category as its value.
- Cox regression analysis was used to adjust estimated incidence rate ratios simultaneously for potentially confounding variables.
- Multivariate analyses of the onset of obesity: adjusted for
  - age (<50, 50-54, 55-59, 60-64, ≥years
  - smoking (never, past, current 1-14, 15-24, ≥25 cigarettes/day
  - alcohol consumption (0, 0.1-4.9, 5-14.9, ≥15 g/day
  - physical activity (METs in quintiles)
  - dietary variables including total energy intake, total fat, glycemic load, and cereal fiber (all in quintiles).
- Multivariate analyses of diabetes, the covariates included age, smoking, alcohol consumption, and family history of diabetes. Further analyses adjusted for dietary intakes of polyunsaturated fat, glycemic load, cereal fiber, and trans fats (all in quintiles).
- The population attributable risk was used to estimate the percentages of obesity and type 2 diabetes cases in this population were attributable to the joint effects of 2 risk factors(either >10h/wk of TV watching or <30 min/d walking or equivalent energy expenditure.
- P=.05 was considered significant.
- Statistical analysis was performed using SAS statistical software, version 8.2(SAS Institute Inc., Cary, NC).

## Data Collection Summary:

### Timing of Measurements

#### Biennial Questionnaire

- A supplemental questionnaire regarding symptoms, diagnostic tests, and hypoglycemia therapy was mailed to women who indicated on any biennial questionnaire that they had been diagnosed with diabetes.
- Body weight was self reported in the biennial questionnaire. Self reported weight were highly correlated with measured weights( $r=0.96$ ; mean difference, 1.5 kg).
- In 1976, the nurses were asked to report their height to the closet inch.
- In 1992, participants were asked to report their average weekly time spent sitting at home while watching TV or VCR, sitting at work away from home or while driving, and other sitting at home(e.g. reading, meal times, at desk).
- They were also asked to report time spent standing or walking around at home or at work.
- In 1992, 1994, and 1996, participants were asked the amount of time they spent on average per week on each of the following activities: walking, jogging, running, bicycling, calisthenics/aerobics/aerobic dancing/rowing machine, lap swimming, squash/racquetball, and tennis.
- They were also asked about their usual walking pace, specified as easy /casual (<2 miles per hour [mph], normal (2-2.9 mph), brisk (3-3.8mph), or very brisk/striding (≥4 mph).

### Dependent Variables

- On-set of obesity
- Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters.
- Incidence of obesity was defined as transition from non-obese (BMI< 30) in 1992 to a BMI of 30 or more at the end of follow-up in 1998.
- Those, only individuals with a BMI of less than 30 across all time points(between 1976 and 1992) were included in the obesity analysis( $n=50,277$ ).
- Type 2 diabetes
- A case of diabetes was considered confirmed if at least 1 of the following was reported on the supplementary questionnaire:

(1) classic symptoms plus elevated glucose levels (a fasting blood plasma glucose concentration  $\geq 140$ mg/dL

[7.7 mmol/L] or a randomly measured concentration of at least 200mg/dL[11.1 mmol/L] ;(2) at least 2 elevated plasma glucose concentrations on different occasions in the absence of symptoms(levels as above or  $\geq$  200mg/dL, [11.1 mmol/L] after $\geq$ 2 hours of oral glucose tolerance testing; and (3)treatment with oral hypoglycemic agents or insulin.

- The researchers stated that the criteria for diabetes classification were consistent with those proposed by the National Diabetes Data Group.
- The validity of this diagnostic procedure were verified in a subsample of the population. In addition, another substudy assessing the prevalence of undiagnosed diabetes suggested a very low rate of false-negative results.

## Independent Variables

Behavior and physical activity:

- The responses included 9 categories (ranging from 0 h/wk to > 90h/wk).
- In the current analyses, 5 categories were coded consistently across all 5 items(0-1, 2-5, 6-20, 21-40, and >40 h/wk).
- From this information, weekly energy expenditure in metabolic equivalent hours (MET-hours) was calculated. For example, brisk walking required an energy expenditure of about 4 METs and was considered to be a moderate-intensity activity.
- In this cohort, walking was the most common type of activity( 60% of all women reported that they walked  $\geq$ 1 h/wk).
- The researchers stated that they only reported baseline analyses because the results using baseline and updated physical activities were similar
- The reproducibility and validity of the physical activity questionnaire have been previously described elsewhere.

## Control Variables

## Description of Actual Data Sample:

**Initial N:** 121,700

**Attrition (final N):**50,277

**Age:** See Table 1

**Ethnicity:**

**Other relevant demographics:**

**Anthropometrics** (e.g., were groups same or different on important measures)

**Location:** United States

## Summary of Results:

### Key Findings: Tables 1, 2, and 3

- During the 6 years of follow-up, 3757(7.5%) of 50277 women who had a BMI of less than 30 in 1992 became obese (BMI  $\geq$ 30).
- Overall, researchers documented 1515 new cases of type 2 diabetes.
- Time spent watching TV was positively associated risk of obesity and type 2 diabetes.
- In the multivariate analysis adjusting for age, smoking, exercise level, dietary factors, and other covariates, each 2-h/d increment in TV watching was associated with a 23% (95 % confidence interval[CI] ,17-30%) increase in obesity and a 14%(95%CI,5%-23%) increase in risk of diabetes; each 2-h/d increment in sitting at

work was associated with a 5%(95% CI, 0%-10%) increase in obesity and a 7%(95% CI, 0%-16%) increase in diabetes.

- In contrast, standing or walking around at home (2-h/d) was associated with a 9% (95% CI, 6%-12%) reduction in obesity and a 12% (95% CI, 7%-16%) reduction in diabetes.
- Each 1 hour per day of brisk walking was associated with a 24% (95% CI, 19%-29%) reduction in obesity and a 34% (95% CI, 27%-41%) reduction in diabetes.
- The researchers estimated that in the cohort, 30% (95% CI, 24%-36%) of the new cases of obesity and 43 % (95% CI, 32%-52%) of new cases of diabetes could be prevented by adopting a relatively active lifestyle (<10h/wk of TV watching and ≥30 min/day of brisk walking).

Table 1. Baseline (1992) Characteristics According to Average Hours Spent watching Television in 68 n497 Women in the Nurses' Health Study <sup>a</sup>

	Hours Spent Watching Television per week				
	0-1 (n=4814)	2-5 (n=16799)	6-20 (n=35884)	21-40 (n=9536)	>40 (n=1464)
Age, y	56(6.7)	57(7.1)	57(7.0)	60(6.9)	61(6.8)
Family history of diabetes, No. (%)	1107(23)	4032(24)	8971(25)	2479(26)	366(25)
Postmenopausal hormone use, No. (%)	1781(37)	6048(36)	13277(37)	3624(38)	498(34)
Current smokers, No. (%)	578(12)	2352(14)	5383(15)	1716(18)	307(21)
Alcohol consumption, g/d	4.7(4.3)	4.9(9.1)	5.3(9.4)	5.6(10.5)	5.4(10.3)
Body mass index	25(4.7)	26(4.8)	26(4.9)	27(5.3)	28(6.0)
Physical activity, METs/wk	21(25.1)	20(25)	19(23)	17(21)	16(21)
Glycemic load	115(4.3)	115(4.2)	117(4.2)	118(4.2)	118(4.8)
Nutrient intake					
Total fat, energy percentage	30.6(6.4)	31.0(6.0)	31.6(5.8)	32.3(6.0)	32.4(6.4)
Trans-fat, energy percentage	1.40(0.60)	1.44(0.57)	1.51(0.57)	1.59(0.59)	1.57(0.60)
Polyunsaturated fat, energy percentage	5.82(1.66)	5.87(1.67)	5.92(1.57)	6.02(1.65)	5.84(1.09)
Monounsaturated fat, energy percentage	11.7(2.8)	11.9(2.6)	12.1(2.5)	12.4(2.6)	12.5(2.8)
Saturated fat, energy percentage	10.3(2.8)	10.5(2.5)	10.7(2.5)	11.0(2.6)	11.2(2.7)
Cereal fiber, g/d	5.74(3.92)	5.50(3.63)	5.56(3.59)	5.49(3.60)	5.18(3.61)
Total calories, kcal/d	1710( 524)	1716(515)	1760(509)	1803(512)	1804(538)
Food intake, servings <sup>†</sup>					
Red meat	0.64(0.51)	0.69(0.51)	0.75(0.52)	0.84(0.58)	0.89(0.69)
Fish	0.31(0.32)	0.32(0.31)	0.31(0.27)	0.29(0.24)	0.30(0.28)
Vegetables	3.69(2.29)	3.67(2.25)	3.50(2.02)	3.39(2.00)	3.36(2.41)
Fruit	2.28(1.57)	2.21(1.60)	2.09(1.33)	1.98(1.36)	1.93(1.54)
Potato	0.34(0.30)	0.35(0.31)	0.38(0.28)	0.40(0.28)	0.40(0.32)
Snack	0.64(1.05)	0.65(0.93)	0.72(0.99)	0.79(1.10)	0.75(1.12)

Whole grain	1.54(1.38)	1.41(1.23)	1.37(1.15)	1.37(1.18)	1.25(1.13)
Refined grain	1.05(0.93)	1.07(0.90)	1.15(0.90)	1.24(0.97)	1.27(1.02)
Sweets	0.93(1.08)	0.98(1.11)	1.07(1.15)	1.19(1.29)	1.19(1.37)

Abbreviations: METs, metabolic equivalents.

\*All dietary factors were assessed in 1990. Data are presented as mean (SD) unless otherwise indicated.

†Red meat includes pork, beef, lamb (main dish and mixed dish), hamburger, processed meat, hot dog, and bacon. Fish includes tuna, dark meat fish, and other fish. Vegetables include tomatoes, tofu, broccoli, string beans, onion, cabbage, cauliflower, sweet potato, brussels sprouts, peas, corn, squash, eggplant, carrot, spinach, kale, celery, lettuce, beets, and mixed vegetables. Fruits include prune, banana, watermelon, cantaloupe, apple, orange, grapefruit, strawberry, blueberry, and peach. Potato includes potatoes (baked, mashed, and fries). Snack includes potato/corn chips, crackers, and popcorn. Whole grains include dark bread, brown rice, cereal, oatmeal, oat bran, wheat germ, and other grain and bran. Refined grain includes white rice, pasta, white bread, pancakes, waffles, muffins, and bagels. Sweets include chocolate, candy, cookie, doughnuts, cake, coffee cake and pie.

Table 2. Relative Risk of Obesity (1992-1998) According to Categories of Sedentary Behaviors

	No. of Hours					
	0-1	2-5	6-20	21-40	>40	P for Trend
Sitting while watching television						
No. of cases	226	872	2043	530	86	
Person-years	21242	70616	148425	36659	5198	
Age-adjusted RR(95% CI)	1.00	1.23(1.06-1.42)	1.42(1.24-1.63)	1.68(1.43-1.96)	2.00(1.56-2.57)	<.001
Multivariate RR(85% CI)*	1.00	1.24(1.07-1.42)	1.44(1.25-1.65)	1.67(1.43-1.96)	1.97(1.53-2.53)	<.001
Multivariate RR(95% CI) †	1.00	1.22(1.06-1.42)	1.42(1.24-1.63)	1.65(1.41-1.93)	1.94(1.51-2.49)	<.001
Sitting at work or away from home or driving						
No. of cases	240	1032	1812	530	143	
Person-years	21947	88720	127931	35 198	8345	
Age-adjusted RR(95% CI)	1.0	0.98(0.85-1.13)	1.08(0.94-1.24)	1.08(0.92-1.26)	1.24(1.01-1.53)	.01
Multivariate RR(85% CI)*	1.0	1.03(0.89-1.18)	1.14(1.00-1.31)	1.14(0.98-1.33)	1.28(1.04-1.58)	.01
Multivariate RR(95% CI) †	1.0	1.02(0.89-1.18)	1.13(0.98-1.29)	1.13(0.96-1.31)	1.25(1.02-1.54)	.02
Other sitting at home‡						
No. of cases	141	1020	2158	352	86	
Person-years	9702	73098	159977	32 676	6688	
Age-adjusted RR(95% CI)	1.00	0.97(0.81-1.15)	0.95(0.80-1.13)	0.84(0.69-1.02)	1.06(0.81-1.38)	.23
Multivariate RR(85% CI)*	1.00	1.00(0.84-1.19)	1.01(0.85-1.20)	0.90(0.74-1.10)	1.11(0.85-1.45)	.49
Multivariate RR(95% CI) †	1.00	0.99(0.83-1.18)	1.01(0.85-1.20)	0.90(0.74-1.10)	1.11(0.85-1.45)	.52

Standing or walking around at home						
No. of cases	89	595	1711	887	475	
Person-years	5087	36871	122197	74407	43579	
Age-adjusted RR(95% CI)	1.00	0.94(0.75-1.17)	0.79(0.64-0.98)	0.69(0.56-0.86)	0.67(0.54-0.84)	<0.001
Multivariate RR(85% CI)*	1.00	0.99(0.79-1.23)	0.87(0.70-1.08)	0.78(0.62-0.97)	0.77(0.61-0.96)	<0.001
Multivariate RR(95% CI †	1.00	0.99(0.79-1.24)	0.87(0.70-1.08)	0.78(0.63-0.97)	0.77(0.61-0.97)	<0.001
Standing or walking around at work						
No. of cases	260	659	1309	1026	503	
Person-years	21768	58364	100699	71 903	29 407	
Age-adjusted RR(95% CI)	1.00	0.87(0.75-1.00)	0.90(0.79-1.03)	0.88( 0.76-1.01)	1.05(0.90-1.22)	.04
Multivariate RR(85% CI)*	1.00	0.91(0.79-1.05)	0.97(0.85—1.11)	0.93(0.81-1.07)	1.12(0.96-1.30)	.03
Multivariate RR(95% CI †	1.00	0.91(0.79-1.05)	0.96(0.84-1.10)	0.92(0.80-1.06)	1.11(0.95-1.29)	.04

Abbreviations: CI, confidence interval; RR, relative risk.

\* Controlled for age, smoking, hormone use, alcohol consumption, and metabolic equivalents.

† Controlled for age, smoking, hormone use, alcohol consumption, metabolic equivalents, total fat, cereal fiber, glycemic load, and total calories.

‡ Reading, mealtime, at desk

Table 3 . Relative Risk of Type 2 Diabetes (1992-1998) According to Categories of Sedentary Behaviors

	No. of Hours					
	0-1	2-5	6-20	21-40	>40	P for Trend
Sitting while watching television						
No. of cases	81	315	810	258	51	
Person-years	27966	97 533	208,138	54970	8293	
Age-adjusted RR(95% CI)	1.00	1.10(0.86-1.40)	1.30(1.04-1.64)	1.53(1.43-1.96)	1.98(1.39-2.81)	<.001
Multivariate RR(85% CI)*	1.00	1.10(0.86-1.41)	1.33(1.06-1.68)	1.49(1.43-1.92)	1.77(1.24-2.52)	<.001
Multivariate RR(95% CI †	1.00	1.09(0.85-1.39)	1.30(1.03-1.63)	1.44(1.12-1.85)	1.70(1.20-2.43)	<.001
Sitting at work or away from home or driving						
No. of cases	130	443	686	192	64	
Person-years	31482	122088	179625	51185	12521	

Age-adjusted RR(95% CI)	1.0	0.91(0.74-1.10)	1.00(0.82-1.20)	1.01(0.81-1.27)	1.37(1.02-1.86)	.01
Multivariate RR(85% CI)*	1.0	1.00(0.82-1.21)	1.12(0.92-1.35)	1.13(0.90-1.42)	1.51(1.11-2.04)	.004
Multivariate RR(95% CI) †	1.0	0.99(0.81-1.20)	1.10(0.91-1.33)	1.12(0.89-1.41)	1.48(1.10-2.01)	.005
Other sitting at home‡						
No. of cases	65	361	852	170	67	
Person-years	14490	102965	223445	46089	9912	
Age-adjusted RR(95% CI)	1.00	0.79(0.61-1.03)	0.85(0.66-1.10)	0.80(0.60-1.06)	1.44(1.02-2.02)	.01
Multivariate RR(85% CI)*	1.00	0.87(0.67-1.13)	1.12(0.77-1.28)	1.13(0.71-1.25)	1.51(1.10-2.19)	.003
Multivariate RR(95% CI) †	1.00	0.87(0.67-1.13)	0.98(0.76-1.26)	0.94(0.70-1.24)	1.54(1.10-2.18)	.004
Standing or walking around at home						
No. of cases	37	264	697	335	182	
Person-years	7944	55261	174845	101200	57649	
Age-adjusted RR(95% CI)	1.00	1.02(0.72-1.44)	0.86(0.62-1.20)	0.71(0.51-1.00)	0.66(0.46-0.94)	<0.001
Multivariate RR(85% CI)*	1.00	1.15(0.81-1.62)	1.05(0.76-1.47)	0.91(0.64-1.27)	0.86(0.60-1.22)	<0.001
Multivariate RR(95% CI) †	1.00	1.13(0.80-1.59)	1.03(0.74-1.44)	0.88(0.63-1.24)	0.83(0.58-1.19)	<0.001
Standing or walking around at work						
No. of cases	156	326	515	365	153	
Person-years	31892	82267	140395	100221	42126	
Age-adjusted RR(95% CI)	1.00	0.83(0.68-1.00)	0.79(0.66-0.95)	0.82( 0.68-1.00)	0.82(0.65-1.04)	.68
Multivariate RR(85% CI)*	1.00	0.92(0.77-1.12)	0.94(0.78—1.13)	0.93(0.77-1.14)	0.95(0.75-1.19)	.93
Multivariate RR(95% CI) †	1.00	0.92(0.76-1.12)	0.93(0.78-1.12)	0.93(0.76-1.13)	0.94(0.74-1.18)	.86

Abbreviations: CI, confidence interval; RR, relative risk.

\*Adjusted for age, hormone use, alcohol consumption, smoking, family history of diabetes, and physical activity.

† Adjusted for age, hormone use, alcohol consumption, smoking, family history of diabetes, physical activity, glycemic load, polyunsaturated fatty acid, cereal fiber, and trans-fat.

‡Reading, mealtime, at desk

#### Author Conclusion:

The major strength of this study includes its large sample size, prospective design, and detailed measures of physical



activity, sedentary behaviors, and a multitude of dietary and nondietary covariates.

**Conclusion:**

- Independent of exercise levels, sedentary behaviors, especially TV watching were associated with significantly elevated risk of obesity and type 2 diabetes, whereas, even light to moderate activity was associated with substantially lower risk.
- This study emphasizes the importance of reducing prolonged TV watching and other sedentary behaviors for preventing obesity and diabetes.

**Limitation:**

- This observational study cannot prove a causal relationship between TV watching behavior and obesity.
- This issue could be addressed in randomized clinical trials in adults

**Reviewer Comments:**

*Analytical longitudinal surveys refer to what epidemiologists term prospective or cohort studies. A Cohort Study is a study in which patients who presently have a certain condition and/or receive a particular treatment are followed over time and compared with another group who are not affected by the condition under investigation. Studies of this kind provide a better opportunity than one time cross sectional studies to examine whether certain behaviors do in fact lead to (or cause) the disease.*

*The limitations and critique of the study, as stated by the authors appear to be very appropriate.*

**Research Design and Implementation Criteria Checklist: Primary Research**

**Relevance Questions**

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

**Validity Questions**

1.	<b>Was the research question clearly stated?</b>	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	<b>Was the selection of study subjects/patients free from bias?</b>	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes



2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
<b>3.</b>	<b>Were study groups comparable?</b>	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	Yes
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes

6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>Yes</b>
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	<b>Yes</b>
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	<b>Yes</b>
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	<b>Yes</b>
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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